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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,851	04/07/2006	Wim Meutermans	MJW-5066-6	9185

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	PAPER NUMBER
1623	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,851	MEUTERMANS ET AL.	
	Examiner	Art Unit	
	Lawrence E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *April 11, 2005 (Preliminary Amendment)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/11/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP §608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

Applicant is respectfully requested to amend the abstract because while the Abstract is in US format, it is not a complete sentence, it is too brief, and it lacks terminal punctuation.

No claims have been cancelled, no claims have been amended, the disclosure has been amended at page 1, and no new claims have been added as per the preliminary amendments filed April 11, 2005. One Information Disclosure Statement (**1** IDS) filed April 11, 2005 has been received with all cited references and made of record.

Examiner's review of the claims revealed two claims numbered "**35.**" Under the authority of 37 C.F.R. §1.126, examiner has renumbered the claims beginning with the second claim **35** for a new total of **39** claims. Applicant is respectfully requested to amend the case records accordingly.

Claims **1-39** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **1-39** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for the substantial number of compounds synthesized and tested and the pharmaceutical compositions thereof, does not reasonably provide enablement for the generic

assertion that the much larger generic class of compounds, method of medicinal treatment wherein same are administered, or the pharmaceutical compositions thereof. In addition, examiner notes that the claim **1** is directed to a generic class of pharmaceutical activities ("inhibiting or effecting the activity of a [G-protein coupled receptor] (GPCR)" with some specific receptors being included as therapeutic targets in dependent claims, but that no specific disease conditions are listed in the claims as being effectively treated by administration of any single compound, or "combination" of compounds, disclosed herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims is found to be excessive because of reliance on numerous variables to be applied to the generic structure to generate a vast array of species, the vast majority of which are not synthesized herein or tested for any disease-specific medicinal activity herein.

B. The nature of the invention: The invention is apparently directed to the treatment of diseases associated with the "GPCR" receptor set (scope undefined) by the administration of compounds as defined by "General Formula I" and to pharmaceutical compositions wherein the active ingredient is also defined by the same General Formula.

C. The state of the prior art: Prior art references presently of record are cited below as anticipating the instant claimed subject matter (pharmaceutical compositions and generic GPCR binding activity).

D. The level of one of ordinary skill: One of ordinary skill would be expected to be familiar with the synthesis of the carbohydrate derivatives claimed as active ingredients herein, and also familiar with the test protocols applied to establish GPCR binding affinity. Examiner assumes that the terms GPCR found herein and "G-protein linked receptors" or "GPLR" found in the prior art patents cited below refer to essentially the same subject matter.

E. The level of predictability in the art: This instant art area is presumed to be unpredictable because of the absence of anyu clear showings that compounds disclosed herein or compounds disclosed in the prior art are effective in the treatment of any diseases.

F. The amount of direction provided by the inventor: The instant disclosure provides directions concerning synthesis of the compounds listed in the claims, and provides some indication that GPCR binding occurs, but does not provide any connection between the latter data and the effective treatment of any disease condition.

G. The existence of working examples: This subject is dealt with in the previous paragraph.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is found to be excessive because the instant disclosure, while providing a lengthy list of compounds and some receptor binding data, does not provide any showing that clearly establishes that the instant claimed method is effective in the treatment of any disease condition, or that the excessive breadth of the compounds asserted to have the claimed activity has been adequately enabled by the instant disclosure.

Claims **1 and 3-13** are objected to because of the following informalities:

In claim **1** at line 6 and claim **4** at line 4, the term "Wherein" is improperly capitalized.

Claims **3 and 5-13** are lacking in terminal punctuation.

Appropriate correction is required.

Claims **1, 2 and 16-38** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** at line 1, the term "GPCR" is incomplete because the acronym has not been defined.

In claim **1** at lines 7, 10, 11 and 15, the term "NR^A" includes a valence error (an amino nitrogen is trivalent, not divalent). Did applicant intend the term to read -- -NHR^A --?

In claim **1** at lines 7-9, 10-11 and12-14, applicant has provided Markush preambles, but has failed to provide the term -- and -- between the last two group members. Markush groups are properly formulated with the term -- selected from the group consisting of [A], [B], ... and [R] --. The same problem reoccurs in claim **2**.

In claim **2** the Markush group beginning at line 2 is populated with substituent groups and also with terms that refer to generic classes of compounds; e.g. "amidine," "imine," "carboxylic acid," "phosphate," "hydroxamic acid," etc., etc. Applicant is respectfully requested to rename all compound names as substituent names or delete as appropriate.

In claims **16-38** each claim makes reference to a "Substituent per Example Library 1-14" in the disclosure. Therefore, each of the noted claims is incompletely defined. Applicant is respectfully requested to define each chemical species claimed herein with variables that are defined within the claim.

Claim **39** is improperly dependent for lack of proper antecedent basis because the claim from which it depends is a "method" claim, not a "composition" claim. Examiner respectfully suggests that deletion of claim dependence and the incorporation of the compound definitions and limitations of claim **1** into claim **39** would be one way to make claim **39** a complete independent claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

(f) he did not himself invent the subject matter sought to be patented."

Claims **1-39** are rejected under 35 U.S.C. §102**(b)** as being anticipated by **Hirschmann et al. '534** (PTO-892 ref. **A**).

Applicant is referred to the teachings of G-protein coupled receptor binding with pharmaceutical compositions at columns 90-92 that read on claims **1-38**, and the claims at column 92 wherein compounds that read on the pharmaceutical compositions of claim **39** are provided.

Claims **1-39** are rejected under 35 U.S.C. §102**(b)** as being anticipated by **Hirschmann et al. '512** (PTO-892 ref. **B**).

Applicant is referred to the teachings of G-protein coupled receptor binding with pharmaceutical compositions at columns 99-101 that read on claims **1-38**, and the claims at column 102 wherein compounds that read on the pharmaceutical compositions of claim **39** are provided.

Claim **39** is rejected under 35 U.S.C. §102**(b)** as being anticipated by **Budavari et al.** (PTO-1449 ref. **AR**).

The compounds listed in the supplied pages from this reference anticipate the instant claimed pharmaceutical composition because both the active ingredients (carbohydrates) reading of the definition of claim **1** and the optional presence of a carrier are disclosed.

The following is a quotation of 35 U.S.C. §103**(a)** which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claim **39** is rejected under 35 U.S.C. §103**(a)** as being unpatentable over **Hirschmann et al. '534** (PTO-892 ref. **A**) in view of **Hirschmann et al. '512** (PTO-892 ref. **B**).

The instant claims are directed to the pharmaceutical compositions of the compounds defined in claim **1**.

Hirschmann et al. '534 (PTO-892 ref. **A**) and **Hirschmann et al. '512** (PTO-892 ref. **B**) disclose compounds that are capable of binding to a G-protein coupled (or linked) receptor when administered thereto as a pharmaceutical composition.

Applicant is requested to note that claiming an unpatentable compound in combination with a carrier does not render the combination patentable if it would be obvious in the prior art to utilize a carrier with the compound: see *Ex parte Billman.*, (POBA 1946), 71 USPQ 253; *In re Lerner* , (CCPA 1971) 438 F2d 1008; 169 USPQ 51; and *In re Rosicky* , (CCPA 1960) 276 F 2d 656, 125 USPQ 341.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the pharmaceutical compositions of the compounds claimed in either the **'534 or '512** patents. .

One having ordinary skill in the art would have been motivated to combine these references because both references disclose clearly overlapping subject matter.

Therefore, the instant claimed methods and the pharmaceutical compositions would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX

(unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
03/30/2009

/Lawrence E. Crane/

Primary Examiner, Art Unit 1623

L. E. Crane
Primary Patent Examiner
Technology Center 1600